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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/712,612      | 11/13/2000  | Duy H. Hua           | 90-99               | 9612             |

23713 7590 07/30/2002

GREENLEE WINNER AND SULLIVAN P C  
5370 MANHATTAN CIRCLE  
SUITE 201  
BOULDER, CO 80303

EXAMINER

FAY, ZOHREH A

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 07/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/712,612**

Applicant(s)  
**Hua et al.**

Examiner  
**Zohreh Fay**

Art Unit  
**1614**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above, claim(s) 8-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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Claims 1-23 are presented for examination.

The response to the restriction requirement of April 11, 2202 has been received and entered.

Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for certain symptoms or conditions resulting from the activity of aldose reductase, does not reasonably provide enablement for the general phrase of “a symptom or condition results from the activity of aldose reductase”. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) At 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex Parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence of absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art,
- 7) the predictability of the art, and

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8) the breadth of the claims.

Applicant fails to set forth the criteria that defines “a symptom or condition results from the activity of aldose reductase’. Additionally applicant fails to provide information allowing the skilled artisan to ascertain these conditions without undue experimentation. The pharmaceutical art is unpredictable, requires each embodiment to be individually assessed for physiological activity. The instant claims read on all “symptoms or conditions results from the activity of aldose reductase”, necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicant fails to provide information sufficient to practice the claimed invention, absent undue experimentation.

Applicant’s arguments regarding the restriction requirement have been carefully considered, but are not deemed to be persuasive. The claims of the instant application are drawn to compounds, compositions and treatment of different disorders. Each of the above groups is capable of supporting it’s own patent. A reference which anticipates the invention of one of the above groups would neither anticipate nor make obvious the invention of any of the other groups. The searches for the above inventions would not be co-extensive particularly as to the required literature search. For the above reasons the restriction for examination purpose is proper and is made final.

Art Unit:

1. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Fay whose telephone number is (703) 308-4604.

ZOHREH FAY  
PRIMARY EXAMINER  
GROUP 1200



Z.F

July 26, 2002